K033000

MAR 2 2 2004

Summary for 50C-0083-1 NPTLOX

Essex Cryogenics of MO., Inc.
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Contact: Elizabeth Hunnicutt
Date of revised summary: 02/24/04

Trade Name: Next Generation Portable Therapeutic Liquid Oxygen System
Common Name: Portable Liquid Oxygen System
Classification Name: Portable Liquid Oxygen Unit
CFR 21 § 868.5655, Product Code: BYJ
Class II
Anesthesiology

Legally Marketed Device which substantial equivalence is claimed:
Portable Therapeutic Liquid Oxygen System (PTLOX)
510(k) K880183

Description: The NPTLOX is a portable, thermally insulated container designed to store liquid oxygen (99.9%) and convert the liquid oxygen to gaseous form, which provides therapeutic oxygen to patients. This equipment meets the Aero-medical mission requirements for gaseous oxygen to be delivered to patients in the three methods listed below.

- 1240 DISS Flow control valves and humidifier bottles
- Laerdal Silicone Adult Resuscitators with 2500 ml reservoirs
- Impact 754 Eagle Ventilators

The NPTLOX has six outlet ports that are capable of delivering oxygen to a maximum of six ambulatory or litter patients according to one or more of these approved methods.

The system will be filled by current liquid oxygen storage/filling systems used in the United States Military. The design of the NPTLOX is a modification to the existing predicate device, the Portable Therapeutic Liquid Oxygen (PTLOX) 510(k) K880183. The major modifications are an improvement in maximum oxygen delivery rate, increased number of patient outlets and increased oxygen capacity.

The NPTLOX provides gaseous oxygen to patients through 6 outlet ports at an outlet pressure of 50 ± 5 psig. The 6 outlet ports have a maximum combined system outlet flow of 66 LPM. This continuous flow rate is based on a design standard of 11 LPM per outlet

fitting. The system is capable of flowing at least 60 LPM to meet the ventilator peak flow requirement. The NPLTOX has an accessory kit that includes three of each of the following: medical hoses, 0-15 LPM flow control valves, and humidifier bottles. The LOX capacity of the system is 20 liters. Oxygen delivery pressure is displayed via a pressure gauge. The LOX quantity can be periodically displayed via a LOX quantity indicator that is powered by two 9 volt batteries. There is no other electronics or software in the NPTLOX.

Indications for use: The NPTLOX is intended to convert liquid oxygen to gaseous oxygen (99.9% based on medical grade liquid oxygen) for delivery at 50 psig nominal for military settings only.

Comparison with the PTLOX: Both devices include a vacuum insulated cryogenics container, with the LOX capacity and the resultant dimensional increase being the significant change. The system has been optimized in the NPTLOX to improve the normal evaporation rate, allowing for less liquid oxygen loss during standby.

Testing: Extensive capability, performance, and environmental testing has been accomplished on the NPTLOX with no issues arising regarding its safety and efficiency. The combined testing and analysis of results provides assurance that the device meets its specifications and is safe and effective for its intended use.

Elizabeth Hunnicutt Feb 27, 2001

Elizabeth Hunnicutt, Quality Engineer/Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 2 2004

Ms. Elizabeth Hunnicutt
Quality Engineer / Regulatory Affairs
Essex Cryogenics of MO., Incorporated
8007 Chivvis Drive
St. Louis, MO 63123-2395

Re: K033000
Trade/Device Name: Next Generation Portable Therapeutic Liquid Oxygen System
Regulation Number: 868.5655
Regulation Name: Portable Liquid Oxygen Unit
Regulatory Class: II
Product Code: BYJ
Dated: February 27, 2004
Received: March 4, 2004

Dear Ms. Hunnicutt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. In addition, if you wish to change or expand your current indications for use to include non-military environments, you will need to submit a new 510(k) premarket notification, and receive FDA clearance prior to marketing the device.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033000

Device Name: Next Generation Therapeutic Liquid Oxygen System

Indications For Use:
The NPTLOX is intended to convert liquid oxygen to gaseous oxygen (99.9% based on medical grade liquid oxygen) for delivery at 50 psig nominal for military use settings only.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033000